Subpart A—Bulk Drugs

§448.10 Bacitracin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Bacitracin is a white to brown, neutral water-soluble polypeptide. It is so purified and dried that:

(i) Its potency is not less than 40 units of bacitracin per milligram.

(ii) [Reserved]

(iii) Its loss on drying is not more than 5 percent.

(iv) Its pH in an aqueous solution containing 10,000 units per milliliter is not less than 5.5 and not more than 7.5.

(v) It passes the identity test.

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, loss on drying, pH, and identity.

(ii) Samples required: 10 packages, each containing approximately 1.0 gram.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed for bacitracin zinc in §436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient 1.0 percent potassium phosphate buffer, pH 6.0 (solution 1), to obtain a stock solution of convenient concentration. Remove an aliquot of the stock solution, add sufficient hydrochloric acid so that the amount of acid in the final solution will be the same as in the reference concentration of the working standard and further dilute with solution 1 to the reference concentration of 1.0 unit of bacitracin per milliliter (estimated).

(2) [Reserved]

(3) *Loss on drying.* Proceed as directed in §436.200(b) of this chapter.

(4) *pH.* Proceed as directed in §436.202 of this chapter, using an aqueous solution containing 10,000 units per milliliter.

(5) *Identity.* Proceed as directed in §436.319 of this chapter.

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§448.10a Sterile bacitracin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Bacitracin is a white to brown, neutral water-soluble polypeptide. It is so purified and dried that:

(i) Its potency is not less than 50 units per milligram. If it is packaged for dispensing, its content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of units of bacitracin that it is represented to contain.

(ii) It is sterile.

(iii) [Reserved]

(iv) It is nonpyrogenic.

(v) Its loss on drying is not more than 5 percent.

(vi) Its pH in an aqueous solution containing 10,000 units per milliliter is not less than 5.5 and not more than 7.5.

(vii) Its residue on ignition is not more than 3.0 percent.

(viii) It passes the identity test.

(ix) Its heavy metals content is not more than 30 parts per million.

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, pyrogens, loss on drying, pH, residue on ignition, identity, and heavy metals.

(ii) Samples required:

(*a*) If the batch is packaged for repacking or for use in the manufacture of another drug:

(*1*) For all tests except sterility: 10 packages, each containing approximately 1 gram.

(*2*) For sterility testing: 1 package, containing approximately 12 grams.

(*b*) If the batch is packaged for dispensing:

(*1*) For all tests except sterility: A minimum of 10 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests ands methods of assay*—(1) *Potency.* Proceed as directed for bacitracin zinc in §436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed